IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Yi Feng Zheng, *et al.*

Serial No.: 10/736,004

Confirmation No.: 2953

Filed: December 15, 2003

Title: Assays for Entactogens

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPELLANT'S REPLY BRIEF

This is a reply to the Examiner's Answer dated December 3, 2007, and the Supplemental Examiner's Answer dated December 27, 2007 (collectively referred to herein as the "Answer"), by the United States Patent and Trademark Office (the "Office") in the above-identified patent application. Appellant's Brief on Appeal (the "Appeal Brief") was filed on July 16, 2007.

The Answer contained several new arguments to which Appellant replies as follows. Appellant refers to the Appeal Brief for addressing any arguments in the Answer not specifically addressed herein.

Claims 25, 27, 30 and 31 Are Separately Patentable

It should be noted that Appellant, in the Appeal Brief, argued that each of claims 25, 27, 30 and 31 are separately patentable over Hui in view of Avenia and over Rouhani in view of Avenia. Appellant maintains that the above claims are separately patentable. In this Reply Brief, Appellant's arguments addressing the new points in the Answer should be viewed as being applied separately for each separately patentable claim to the extent that the points raised in the Answer apply to each separately patentable claim. Appellant hereby maintains and reasserts the arguments in the Appeal Brief not specifically addressed in the Answer for each of the separately patentable claims.

Argument in the Answer Concerning Avenia's Disclosure of Non-preferred Embodiments

The Answer contends that all disclosures of non-preferred embodiments must be considered referring to the disclosure of Avenia, col 5, lines 35-58. At the cited paragraph Avenia indicates that labeled phenethylamine may be radioisotopically labeled phenethylamine and further states that phenethylamines labeled with other detectable labels such as chromophores, fluorophores, enzymes, etc., may be used. The Answer refers to, among others, *In re Lamberti, et al.*, 192 USPQ 278 (CCPA 1976) (*Lamberti*) in support of the above contention.

When conducting an analysis under *Graham* v. *John Deere Co. of Kansas City*, 383 U. S. 1, 148 USPQ 459 (1966) (*John Deere*), the scope and content of the prior art are determined; differences between the prior art and the claims at issue are ascertained; and the level of ordinary skill in the pertinent art is resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. According to *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. _____, 127 S. Ct. 1727, 82 U.S.P.Q. 1385 (2007) (*KSR*), a proper question to ask in conducting an analysis under *John Deere* is whether one of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading the known product. (*KSR*, 82 U.S.P.Q. (BNA) 1385, at 1398, where the court stated that the "proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.")

In the present situation, one skilled in the art, at the time the present invention was made, would not have seen a benefit in preparing any enzyme-labeled phenethylamines. Avenia teaches that the radioimmunoassay, which uses radiolabeled material, is superior in all cases that can be compared (referring to among others, an enzyme label immunoassay; Avenia, col. 11, ln 1-3, and col. 12, ln 1-3). Furthermore, one skilled in the art would not have seen any benefit in preparing an enzyme-labeled phenethylamine having a $-(CH_2)_nC(O)$ linking moiety because of Avenia's remarks concerning the superiority of the radiolabeled phenethylamines. Therefore, the statement in the Answer that, once an activated hapten is known, it is obvious to one of ordinary skill in the art to conjugate label or carrier at the activated site of the hapten, is not convincing. According to Avenia, there would be no benefit realized by one skilled in the art in making the aforementioned modification of the prior art teaching in the manner suggested in the Answer. In the present situation, one might view the scope and content of the prior art as teaching away from the instantly claimed invention.

Furthermore, Appellant submits that Avenia's teaching goes beyond a mere listing of "non-preferred" embodiments. The rejection is under 35 U.S.C. 103(a) wherein patentability is negatived if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. The differences between the presently claimed subject matter and Avenia in the present situation include not only that the label is an enzyme, but also that the enzyme of the enzyme conjugates employed in the present methods is linked to the amphetamine or methamphetamine by the subject linking moiety. The labeled phenethylamines, to which Avenia refers, are not ones that contain the linking moiety as claimed for the enzyme conjugate used in the present method claims. As can be seen, for example, from Avenia, col. 10, lines 26-34, 4-hydroxy-alpha-methylphenethylamine hydrobromide was iodinated with $Na^{125}I$ and chloramine T. As a matter of fact, Avenia seems to maintain a demarcation between the labeled phenethylamines, to which the patentee refers, and the hapten coupled immunogenic carriers, which the patentee employs to prepare antibodies. Although Avenia states that enzymes may be suitable labels (Avenia, col 4, ln 57-58), it is only within the context of labeled phenethylamines as disclosed (Avenia, col 4, ln 47-58). The labeled derivatives that Avenia employs apparently do not

employ a -$(CH_2)_nC(O)$ linking moiety, which is only disclosed for Avenia's novel antigens for forming antibodies (Avenia, col 4, ln 59, to col 5, ln 10).

Finally, there is a distinction in the facts of *Lamberti* and the present situation. In *Lamberti*, the teaching concerning preferred and non-preferred embodiments related to the nature of a thioether reactant that was used to form the product of the patent. The preferred embodiment was a symmetric dialkyl thioether reactant as opposed to an asymmetric dialkyl thioether reactant. In the present situation, it is enzyme-labeled phenethylamine itself, not a reactant in its preparation, which the Answer designates as a "non-preferred" embodiment. More importantly, Avenia arguably teaches away from the very method that Appellant claims. Distinctions between factual situations is important especially when conducting an analysis under *John Deere* because such distinctions go directly to the issue of the scope and content of the prior art and to the determination of the differences between the prior art and the claims at issue.

Argument in the Answer Concerning the Obviousness of Trying Different Immunoassay Formats

At the bottom of page 9 of the Answer, the following conclusory statement is made: "Therefore, since antibody and labeled conjugates are disclosed for phenethylamine, one of ordinary skill in the art would obviously try different immunoassay formats as taught by Hui or Rouhani with the labeled conjugate as suggested by Avenia in order to develop a sensitive non-radiolabeled detection assay because Hui or Rouhani also are concerned with the non-radiolabeled immunodetection of phenethylamine in a sample." The question such a statement raises is, given Avenia's teaching that the radioimmunoassay using the radiolabeled phenethylamine described is superior, in all cases compared, to an enzyme immunoassay employing an enzyme-labeled phenethylamine, why would one skilled in the art have any expectation or belief that a more sensitive assay could be developed if one were to use an enzyme-labeled phenethylamine that employs a -$(CH_2)_nC(O)$ linking moiety. Again, according to *KSR*, there must be some benefit that one skilled in the art would foresee at the time the invention was made.

CONCLUSION AND RELIEF SOUGHT

Appellant has demonstrated above and in the Appeal Brief that claims 25, 27, 30 and 31 are each separately patentable over Hui in view of Avenia and over Rouhani in view of Avenia.

Accordingly, Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the following rejections:

(a) the separate rejections under 35 U.S.C. 103(a) of claims 25, 27, 30 and 31, respectively, as being unpatentable over Hui in view of Avenia and

(b) the separate rejections under 35 U.S.C. 103(a) of claims 25, 27, 30 and 31, respectively, as being unpatentable over Rouhani in view of Avenia.

Respectfully submitted,

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